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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/901,812	07/10/2001	Diane Pennica	GENENT.083A	7879

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GENENTECH, INC.  
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EXAMINER

RAWLINGS, STEPHEN L

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 10/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/901,812

Applicant(s)

PENNICA ET AL.

Examiner

Stephen L. Rawlings, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-66 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *election facsimile cover sheet*.

### DETAILED ACTION

1. Claims 1-66 are pending in the application and are currently subject to the following restriction.

#### ***Election/Restrictions***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Groups 1-10. Claims 1-10, insofar as the claims are drawn to a method for the selective enhancement of the expression of 4-1BB ligand in a tumor cell comprising treating the tumor cell with a retinoid, wherein said tumor is one (1) of the human cancers selected from the group consisting of (1) ovarian cancer, (2) endometrial cancer, (3) Wilm's kidney tumor, (4) colon cancer, (5) breast cancer, (6) prostate cancer, (7) gastric cancer, (8) lung cancer, (9) hepatocellular cancer, and (10) melanoma, classified in class 435, subclass 375.

Groups 11-20. Claims 1-10, insofar as the claims are drawn to a method for the selective enhancement of the expression of ephrin b1 in a tumor cell comprising treating the tumor cell with a retinoid, wherein said tumor is one (1) of the human cancers selected from the group consisting of (1) ovarian cancer, (2) endometrial cancer, (3) Wilm's kidney tumor, (4) colon cancer, (5) breast cancer, (6) prostate cancer, (7) gastric cancer, (8) lung cancer, (9) hepatocellular cancer, and (10) melanoma, classified in class 435, subclass 375.

Groups 21-30. Claims 1-10, insofar as the claims are drawn to a method for the selective enhancement of the expression of ISLR in a tumor cell comprising treating the tumor cell with a retinoid, wherein said tumor is one (1) of the human cancers selected from the group consisting of (1)

ovarian cancer, (2) endometrial cancer, (3) Wilm's kidney tumor, (4) colon cancer, (5) breast cancer, (6) prostate cancer, (7) gastric cancer, (8) lung cancer, (9) hepatocellular cancer, and (10) melanoma, classified in class 435, subclass 375.

Groups 31-40. Claims 1-10, insofar as the claims are drawn to a method for the selective enhancement of the expression of autotaxin in a tumor cell comprising treating the tumor cell with a retinoid, wherein said tumor is one (1) of the human cancers selected from the group consisting of (1) ovarian cancer, (2) endometrial cancer, (3) Wilm's kidney tumor, (4) colon cancer, (5) breast cancer, (6) prostate cancer, (7) gastric cancer, (8) lung cancer, (9) hepatocellular cancer, and (10) melanoma, classified in class 435, subclass 375.

Groups 41-50. Claims 1-10, insofar as the claims are drawn to a method for the selective enhancement of the expression of Stra6 in a tumor cell comprising treating the tumor cell with a retinoid, wherein said tumor is one (1) of the human cancers selected from the group consisting of (1) ovarian cancer, (2) endometrial cancer, (3) Wilm's kidney tumor, (4) colon cancer, (5) breast cancer, (6) prostate cancer, (7) gastric cancer, (8) lung cancer, (9) hepatocellular cancer, and (10) melanoma, classified in class 435, subclass 375.

Groups 51-60. Claims 11-34 and 64, insofar as the claims are drawn to a method for the treatment of a tumor comprising treating the tumor with a combination of a retinoid and an antitumor agent, and an article of manufacture comprising said antitumor agent, wherein said antitumor agent targets 4-1BB ligand and wherein said tumor is one (1) of the human cancers selected from the group consisting of (1) ovarian cancer, (2) endometrial cancer, (3) Wilm's kidney tumor, (4) colon cancer, (5)

breast cancer, (6) prostate cancer, (7) gastric cancer, (8) lung cancer, (9) hepatocellular cancer, and (10) melanoma, classified in class 514, subclass 725.

Groups 61-70. Claims 11-34 and 64, insofar as the claims are drawn to a method for the treatment of a tumor comprising treating the tumor with a combination of a retinoid and an antitumor agent, and an article of manufacture comprising said antitumor agent, wherein said antitumor agent targets ephrin b1 and wherein said tumor is one (1) of the human cancers selected from the group consisting of (1) ovarian cancer, (2) endometrial cancer, (3) Wilm's kidney tumor, (4) colon cancer, (5) breast cancer, (6) prostate cancer, (7) gastric cancer, (8) lung cancer, (9) hepatocellular cancer, and (10) melanoma, classified in class 514, subclass 725.

Groups 71-80. Claims 11-34 and 64, insofar as the claims are drawn to a method for the treatment of a tumor comprising treating the tumor with a combination of a retinoid and an antitumor agent, and an article of manufacture comprising said antitumor agent, wherein said antitumor agent targets ISLR and wherein said tumor is one (1) of the human cancers selected from the group consisting of (1) ovarian cancer, (2) endometrial cancer, (3) Wilm's kidney tumor, (4) colon cancer, (5) breast cancer, (6) prostate cancer, (7) gastric cancer, (8) lung cancer, (9) hepatocellular cancer, and (10) melanoma, classified in class 514, subclass 725.

Groups 81-90. Claims 11-34 and 64, insofar as the claims are drawn to a method for the treatment of a tumor comprising treating the tumor with a combination of a retinoid and an antitumor agent, and an article of manufacture comprising said antitumor agent, wherein said antitumor

agent targets autotaxin and wherein said tumor is one (1) of the human cancers selected from the group consisting of (1) ovarian cancer, (2) endometrial cancer, (3) Wilm's kidney tumor, (4) colon cancer, (5) breast cancer, (6) prostate cancer, (7) gastric cancer, (8) lung cancer, (9) hepatocellular cancer, and (10) melanoma, classified in class 514, subclass 725.

Groups 91-100. Claims 11-34 and 64, insofar as the claims are drawn to a method for the treatment of a tumor comprising treating the tumor with a combination of a retinoid and an antitumor agent, and an article of manufacture comprising said antitumor agent, wherein said antitumor agent targets Stra6 and wherein said tumor is one (1) of the human cancers selected from the group consisting of (1) ovarian cancer, (2) endometrial cancer, (3) Wilm's kidney tumor, (4) colon cancer, (5) breast cancer, (6) prostate cancer, (7) gastric cancer, (8) lung cancer, (9) hepatocellular cancer, and (10) melanoma, classified, respectively, in class 514, subclass 725, or which cannot be classified because the biologic and chemical nature of said antitumor agent is not specified.

Group 101. Claims 35-45, insofar as the claims are drawn to a method for identifying a gene target for tumor treatment comprising determining the gene expression profile of a cell, wherein said gene expression profile is determined by reverse transcriptase-PCR, classified in class 435, subclass 91.2.

Group 102. Claims 35-45, insofar as the claims are drawn to a method for identifying a gene target for tumor treatment comprising determining the gene expression profile of a cell, wherein said gene expression profile is determined by *in situ* hybridization, classified in class 435, subclass 6.

Group 103. Claims 35-45, insofar as the claims are drawn to a method for identifying a gene target for tumor treatment comprising determining the gene expression profile of a cell, wherein said gene expression profile is determined by Northern blotting, classified in class 435, subclass 6.

Group 104. Claims 46-61 and 64, drawn to a method for the treatment of a tumor in a mammalian subject comprising determining the gene expression profile of a sample of a tumor to identify a gene, the expression of which is enhanced by incubating the sample with a retinoid, and treating the subject with a combination of a retinoid and an antitumor agent and an article of manufacture comprising said antitumor agent, classified, respectively, in class 514, subclass 725, or which cannot be classified because the biologic and chemical nature of said antitumor agent is not specified.

Group 105. Claims 62 and 63, insofar as the claims are drawn to a method for diagnosing a cancer comprising detecting 4-1BB ligand, classified in class 435, subclass 7.1.

Group 106. Claims 62 and 63, insofar as the claims are drawn to a method for diagnosing a cancer comprising detecting ephrin b1, classified in class 435, subclass 7.1.

Group 107. Claims 62 and 63, insofar as the claims are drawn to a method for diagnosing a cancer comprising detecting ESLR, classified in class 435, subclass 7.1.

Group 108. Claims 62 and 63, insofar as the claims are drawn to a method for diagnosing a cancer comprising detecting autotaxin, classified in class 435, subclass 7.1.

Group 109. Claims 62 and 63, insofar as the claims are drawn to a method for diagnosing a cancer comprising detecting Stra6, classified in class 435, subclass 7.1.

3. The inventions are distinct, each from the other because of the following reasons:

The inventions in groups 1-109 are disclosed as materially different methods that differ at least in objectives, method steps, reagents and/or doses and/or schedules used, response variables, assays for end products and/or results, and criteria for success, and therefore the claimed methods are distinct.

The inventions in groups 51-100 and 104 and groups 1-50, 101-103, and 105-109 are not at all related because the products of groups 51-100 and 104 are not specifically used in any of the steps of the claimed methods in groups 1-50, 101-103, and 105-109.

4. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Claim 1 is a linking claim, linking the corresponding inventions of claim 1, wherein said tumor is selected from the group of human cancers consisting of (a) ovarian cancer, (b) endometrial cancer, (c) Wilm's kidney tumor, (d) colon cancer, (e) breast cancer, (f) prostate cancer, (g) gastric cancer, (h) lung cancer, (i) hepatocellular cancer, and (j) melanoma.

Claim 11 is a linking claim, linking the corresponding inventions of claim 11, wherein said tumor is selected from the group of human cancers consisting of (a) ovarian cancer, (b) endometrial cancer, (c) Wilm's kidney tumor, (d) colon cancer, (e)



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breast cancer, (f) prostate cancer, (g) gastric cancer, (h) lung cancer, (i) hepatocellular cancer, and (j) melanoma.

Claim 35 is a linking claim, linking the inventions of claim 35, wherein the process of said determining the gene expression profile of the cell comprises a determination by a method selected from the group consisting of (a) RT-PCR, (b) *in situ* hybridization, and (c) Northern blotting.

The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

**Conclusion**

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.  
Examiner  
Art Unit 1642

  
STEPHEN RAWLINGS

slr  
October 1, 2003



# RESTRICTION ELECTION FACSIMILE TRANSMISSION

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